The '285 patent does not render the claims obvious because it addresses a different problem and in modifying the formulations described in the '285 patent in order to reach the present claims would render those formulas inoperable for their intended use.

Applicant continues to traverse the rejection of claims 52-55 on grounds related to the question of what is legally obvious. The compositions described in the '285 patent have to be looked at and considered as a whole. Rather than considering the compositions as a whole, the Action picks out specific ingredients from the '285 formulations that are also in the claimed compositions. This is merely hindsight reconstruction of the claimed invention and is impermissible. The Action points to no reason or motivation to pick out those particular elements other than Applicant's claims. A proper analysis of obviousness must also consider the problem being solved by the present claims, the problem addressed in the prior art, and whether there is motivation in the prior art itself to modify the prior art in order to reach the claimed invention. In doing so, one cannot modify the prior art so that it is not operable for its intended purpose.

> It is generally settled that the change in prior art device which makes the device inoperable for its intended purpose cannot be considered to be an obvious change. *Hughes Aircraft Co v. United States* , 215 U.S.P.Q. 787, 804 (Ct.Cl. Trial Div. 1982) modified (to affirm validity and reverse infringement holding), 717 F.2d 1351 [219 USPQ 473] (Fed. Cir. 1983)

Looking first at the '285 patent, the inventors of this patent appear to be trying to solve the problem of malnutrition in patients with chronic lung diseases (Col 1, line 17 begins a discussion of malnutrition problems in chronic respiratory disease and lung failure). The background section then describes the problems associated with diets in which the calories are primarily derived from carbohydrates and the advantages of a diet in which a majority of calories are derived from fats. The nutritional needs of patients with pulmonary disease are listed in

column 2, beginning on line 17. Column 3 describes the problem of malnutrition due to reduced nutrient intake beginning on line 3 and a discussion follows regarding the effects on losses of diaphragm function and immune function as well as other problems including weight loss. This section concludes with the statement:

> The liquid nutritional product for enteral feeding of the present invention has been formulated to at least reduce the severity of the above described pulmonary related problems which are associated with nutrition. (col. 4, line 6)

In contrast, the present invention addresses the problem of providing off the shelf dietary supplements to reduce inflammatory symptoms while avoiding an increase in serum arachidonic acid. Because the inventors of the '285 patent were addressing a very different problem than Applicant, the enteral formulation, shown in column 16 as Table 7 in no way suggests the formula of the present claims. For example, the formula shown in Table 7 includes only about 36.84 grams total of marine and borage oils. Assuming water weighs about 1 gram per ml, the formula contains less than 5% by weight total marine and borage oils and less than 12% total oils. In contrast, the claimed formulas contain a total of about 35% oils (Claim 52). Even the oil blend of the '285 patent does not suggest the claimed compositions in that most of the oils in the '285 oil blend are not relevant to the present claims.

The Action states that optimizing the effective amounts of active ingredients is within the routine skill in the art, citing *In re Boesch*. Applicant does not understand the relevance of *In re Boesch* to the present application. In *Boesch*, the claims are drawn to a range of concentrations of ingredients in an alloy that fall within ranges described in the prior art. In the present case, the claimed compositions with 35% oils fall well outside the compositions having less than 12% oils in the cited art. They are completely different compositions.

The question here is not optimization, but rather, is there motivation in the '285 patent to modify those compositions to arrive at the claimed compositions, and if those modifications were made, would the '285 compositions work for their intended purpose? Applicant submits that the answer to those questions is no.

Applicant finds no motivation in the '285 patent to modify its disclosure to produce the claimed invention. Applicant finds, in fact, no motivation to produce anything less than the entire nutritional formulation described in the '285 patent. It is Applicant's belief that increasing the amounts of marine and borage oils in the '285 compositions would require a simultaneous reduction in other necessary nutrients that are contained in the '285 formulations. Such compositions would not be complete nutritional products that would solve the problems associated with malnutrition that are the essence of the '285 patent, and would thus not function for their intended purpose.

Because there is no motivation to modify the formulas of the '285 patent, and because to make such modifications would render the compositions inoperable for their intended purpose, the '285 patent cannot render the present claims obvious.

The citation of Igarashi and Kahn regarding the use of certain ingredients as food additive do not remedy the deficiencies of the '285 patent as obviating prior art.

Withdrawal of all rejections under §103 is respectfully requested.

Claim 55 further limits the subject matter of claim 52 and is thus a proper dependent claim.

In order for claim 55 to be narrower than claim 52, there must be an embodiment that falls within the scope of claim 52, but not within the scope of claim 55. The present claims meet that test. For example, a composition having all the elements of claim 52, including less than 1

weight percent minor ingredients that did not include one of xanthan gum, colorant, sorbic acid or ascorbyl palmitate (elements of claim 55) as one of those minor ingredients would infringe claim 52, but not claim 55. Claim 55 is therefore more narrow and is properly dependent on claim 52.

Withdrawal of the objection is respectfully requested.

Weight percent is a well known term in the art and is not indefinite.

The Action rejects claim 52 as indefinite for use of the term 19.29 weight percent. Weight percent is well defined in the art and is equal to (weight of ingredient (water in this case) x 100%) ÷ total weight of entire solution or composition. The total of the ingredients is about 100% within experimental error. Applicants request withdrawal of this rejection.

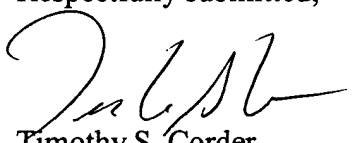
Minor ingredients is a well known term in the art and does not render claim 52 indefinite.

Applicant has used the term minor ingredient as is well known in the art. The claims indicate that the minor ingredients are present at less than 1% of the total weight of the composition. Minor ingredients are described in *Remington: The Science and Practice of Pharmacy*, 19th Edition, Vol II. Mack Publishing Co., Easton, PA, 1995, pg 1380 as substances of little or no therapeutic value that are useful in the compounding of pharmaceuticals. Although Applicant traverses the rejection, in order to progress the case to allowance, the minor ingredients have been further characterized in claim 52. Support for this amendment can be found at least on page 7, the paragraph beginning on line 4, (emulsifiers, antioxidants, stabilizers), at the table in Example 11 on page 45, (colorants), and at page 20, the paragraph beginning on line 21, (emulsifiers, preservatives, anti-oxidants, coloring agents).

It is Applicant's belief that the claims are in condition for allowance and such favorable action is respectfully requested.

If the Examiner has any questions or suggestions that would help the present application proceed more quickly to allowance, a telephone call to the undersigned is earnestly solicited.

Respectfully submitted,



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